

a polymeric bonding layer (18) positioned over and contacting at least the coil (14), wherein the polymeric layer (18) is heat-shrinkable tubing comprising at least one of nylon, polyurethane and PTFE; and

an inner liner (20) beneath and in contact with at least part of the coil (14), the liner (20) comprising PTFE;

wherein the polymeric layer (18) maintains the coil (14) in the stressed, radially expanded condition by adhesion to the coil (14) by thermal bonding to it; and

wherein the tube (11) has an outer diameter no greater than about 1 mm.

20. (Amended) The improvement in a medical device (10) including a tube (11), characterized in that the tube (11) comprises:

a coil (14) in a stressed, radially expanded condition;

a braid (16) extending over at least part of the coil (14); and

a polymeric layer (18) positioned over and contacting at least the coil (14);

wherein the polymeric layer (18) maintains the coil (14) in the stressed, radially expanded condition.

21. (Amended) A tube (11) for use with a medical device (10), the tube (11) comprising a coil (14) in a stressed, radially expanded condition; a braid (16) extending over at least part of the coil (14), and polymeric material (18) positioned at least over the coil (14); the polymeric material (18) at least in part maintaining the coil (14) in the stressed, radially expanded condition.

REMARKS

Response To Election Requirement

In the subject Office Action, the Examiner indicates that the application contains claims directed to three patentably distinct species. Furthermore, the Examiner asserts that the application currently does not contain any generic claim that links the distinct species of the claimed invention.

Applicants respectfully traverse this characterization of the invention. In the election requirement, the Examiner indicated species A as corresponding to FIGS. 1

and 2, species B as corresponding to FIG. 3, and species C as corresponding to FIG. 4. Applicants respectfully assert that each of these indicated species contain the invention. Specifically, each of the indicated species includes a tube 11 according to the present invention. FIGS. 1 and 2 are directed at a first embodiment of the invention, and FIG. 3 is directed at another embodiment of the invention. FIG. 4 illustrates a specific example of a medical device that incorporates the tube of the present invention. Thus, each of the indicated species includes the tube 11 as a common element.

Indeed, Claim 1 as filed is generic and links each of the asserted species. Claim 1 is directed at a medical device that comprises a tube that comprises a coil in a stressed, radially expanded condition, a braid extending over at least part of the coil, and a polymeric layer positioned over and contacting at least the coil. The polymeric layer maintains the coil in the stressed, radially expanded condition. Each of the elements of claim 1 is clearly illustrated in each of the species asserted by the Examiner. Thus, claim 1 reads directly on species A (FIGS. 1 and 2), species B (FIG. 3), and species C (FIG. 4).

All other independent claims in the application simply vary in scope, and do not define different species of the invention. As a result, Applicants respectfully traverse the election requirement, and request that the Examiner reconsider and withdraw this requirement.

In the event the Examiner maintains the election requirement, Applicants hereby confirm the election of species A (FIGS. 1 and 2). Claims 1-12, 14, and 19-21 read on this species. This election is made only to expedite prosecution of this application, and does not indicate any agreement by applicants with the characterization of the invention or with the asserted lack of a generic claim. In the event the Examiner withdraws the election requirement, Applicants request examination of all pending claims on the merits.

Rejection Of Claims Under 35 U.S.C. § 112

The Examiner rejected claims 1-12, 14, and 19-21 under the second paragraph of 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the

Examiner indicated that the phrase "its stressed" in claims 1, 2, and 19-21 lacks sufficient antecedent basis.

To more particularly point out and distinctly claim the subject matter which Applicants regard as the invention, Applicants herein amend claims 1, 2, and 19-21 to change "its stressed" to "the stressed." The phrase "the stressed" in each of these claims finds proper antecedent basis in the initial recitation of the coil element in the appropriate independent claim.

Applicants respectfully assert that the amendments made herein overcome the rejection of these claims under 35 U.S.C. § 112, and request that the Examiner reconsider and withdraw these rejections.

Rejections Of Claims Under 35 U.S.C. § 102

The Examiner rejected claims 1-7, 12, and 20-21 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,462,523 to Samson et al. for a DRUG DELIVERY SYSTEM ("the '523 patent"). The '523 patent is directed at perfuser tips for use with medical devices. The perfuser tips of the '523 patent allow for the passage of an agent from the interior of an associated medical device to the environment external to the device, such as the interior lumen of a body vessel. As illustrated in the figures, the perfuser can be a stiffener 120 with slits 122 (FIGS. 4 and 5) or a coil 118 (FIG. 2). In the embodiment that utilizes a coil 118, a braid 112 can be used in conjunction with the coil 118. The combination of the coil 118 and braid 112 provides a series of passages through which an agent, such as a liquid, can pass from the interior of the device to the exterior environment.

Applicants' invention is directed at medical devices that comprise a tube having a coil in a stressed, radially expanded condition, a braid extending over at least a portion of the coil, and a polymeric layer positioned over and contacting at least the coil. The polymeric layer maintains the coil in the stressed, radially expanded condition.

In order to properly serve as a basis for rejection as an anticipatory reference under 35 U.S.C. § 102(b), the asserted reference must disclose each and every limitation of the rejected claim. The Examiner asserts that the '523 patent discloses a polymeric layer 108 positioned over and contacting the coil. Applicants respectfully

disagree with this characterization of the '523 patent. The '523 patent teaches no such polymeric layer, and reference 108 refers to a catheter body that surrounds the assembly. Indeed, the catheter body 108 cannot contact the coil 118 at all, as it is a solid member and a braid 112 is positioned on top of the coil 118. As clearly illustrated in the figures, the braid 112 physically separates the coil 118 and the catheter body 108. Due to this separation, the catheter body 108 cannot contact the coil 118.

The Examiner also asserts that the catheter body 108 maintains the coil 118 in a stressed position. Without touching the coil, as delineated above, it is unlikely that the catheter body 108 maintains the coil 118 in a stressed position.

Indeed, careful review of the text of the '523 patent, in addition to the figures, reveals a complete lack of any polymeric layer positioned over and contacting at least the coil. Furthermore, the '523 patent does not disclose a coil in a stressed position, maintained in that position by a polymeric layer or any other element.

Pending independent claims 1, 19 and 20 of the present application specifically require that the polymeric layer contact the coil, and maintain the coil in the stressed, radially expanded configuration. Since the '523 patent does not disclose either of these limitations, it cannot properly serve as a basis for rejection under 35 U.S.C. § 102(b) for any pending claim. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection of the claims under 35 U.S.C. § 102(b).

Rejection Of Claims Under 35 U.S.C. § 103(a)

The Examiner rejected claims 8-11 and 19 under 35 U.S.C. § 103(a) as being unpatentably obvious over the '523 patent in view of U.S. Patent No. 6,053,903 to Samson for a HIGH PERFORMANCE SPIRAL WOUND CATHETER ("the '903 patent"). In the rejection of these claims, the Examiner utilizes the '523 patent for the disclosure of a metal coil in a stressed, radially expanded condition, a braid, and a polymeric layer positioned over and contacting the coil. The Examiner acknowledges that the '523 patent does not teach a polymeric layer made from nylon, polyurethane, PTFE, or a heat shrinking tube with thermally bonded coil. The Examiner utilizes the '903 patent for the teaching of these types of polymeric layers, and combines the '523 and '903 patents as a basis for rejection under § 103.

As indicated above, the '523 patent does not disclose each and every limitation of any of the independent claims of the pending application. Specifically, the '523 reference does not disclose a polymeric layer positioned over and contacting at least the coil. Furthermore, the '523 patent does not disclose a coil maintained in a stressed position by a polymer layer or any other element. The '903 patent does not cure these defects. Indeed, the '903 patent is completely devoid of any teaching or suggestion of a polymeric layer that is positioned over and contacting at least the coil. The '903 patent also does not disclose a coil in a stressed position, maintained by a polymeric layer or any other element. Accordingly, the combination of the '523 and '903 patents does not produce each and every limitation of the claimed invention, and therefore cannot properly serve as a basis for rejection of any claim under § 103.

Even if the '523 and '903 patents did disclose each and every limitation of the claimed invention, neither reference contains any suggestion or motivation to combine these references. A skilled artisan would not be motivated to combine either reference with the other.

Accordingly, Applicants respectfully assert that the combination of the '523 and '903 patents cannot properly serve as a basis for rejection under 35 U.S.C. § 103(a), and request that the Examiner reconsider and withdraw these rejections.

The Examiner also rejected claim 14 under 35 U.S.C. § 103(a). In this rejection, the Examiner utilized the '523 patent in combination with U.S. Patent No. 5,769,830 to Parker for a SOFT TIPPED GUIDING CATHETER ("the '830 patent"). Again, the Examiner relied on the '523 patent for the teaching of a tube that comprises a coil in a stressed, radially expanded condition, a braid, and a polymeric layer positioned over and contacting the coil. The Examiner acknowledged that the '523 patent does not teach a polymeric layer with two segments of differing durometers. The Examiner relied on the '830 patent to cure this defect of the '523 patent.

As discussed above, the '523 patent does not disclose each and every limitation of any of the independent claims of the pending application. Specifically, the '523 patent does not disclose a polymeric layer positioned over and contacting at least the coil. Furthermore, the '523 patent does not disclose a coil in a stressed position, maintained by a polymeric layer or any other element. The '830 patent does not cure

these defects. Indeed, the '830 patent is completely devoid of any teaching or suggestion of a polymeric layer that is positioned over and contacting at least the coil. The '830 patent also does not disclose a coil in a stressed position, maintained by a polymeric layer or any other element. Accordingly, the combination of the '523 and '830 patents does not produce each and every limitation of any of the independent claims of the present application.

Even if the '523 and '830 patents did disclose each and every limitation of the claimed invention, neither reference contains any suggestion or motivation to combine these references. A skilled artisan would not be motivated to combine either reference with the other.

Accordingly, this combination of references cannot properly serve as a basis for rejection under 35 U.S.C. § 103(a) for any pending claim, including claim 14. Applicants respectfully request that the Examiner reconsider and withdraw this rejection of claim 14.

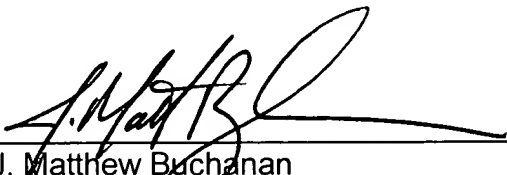
Applicants believe all pending claims, as amended, define patentable subject matter, and request that the Examiner reconsider and withdraw his rejections.

Applicants believe this reply and amendment to be fully responsive to the Office Action mailed on September 12, 2002. If the Examiner believes that personal communication would advance the prosecution of this application, Applicants respectfully request that the Examiner contact their attorney at the number listed below.

Respectfully submitted,

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By: _____


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